REMARKS

Prior to this amendment, claims 1-13, 17, and 19 were pending. In this Response, claims 1 and 17 have been amended for the reasons detailed below, and claims 20 and 21 have been added.

Claim 1 has been amended such that q now represents 3 or 4. With reference to the published PCT application (WO2004/089373, which is identical to the application as originally-filed), basis for this amendment can be found on page 4, line 14 to 16.

Claim 17 has been amended to recite a list of specific diseases. Basis can be found on page 8, line 36 to page 9, line 1. The claim has also been amended to recite that the treatment is of a human subject. Basis can be found on page 9, line 11.

Claim 20 is has been added and identifies Alzheimer's disease as an example of a neurological disease. Basis can be found, for example, on page 8, line 39 and on page 9, lines 32 to 34.

Claim 21, identifying cognitive deficeit of schizophrenia has basis on page 8, line 42 to page 9, line 1.

Applicants wish to thank the Examiner for the thorough and thoughtful review of the application and the prior art.

A. Claim 17 Complies with 35 USC §112, 1st ¶

Claim 17 was rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

The Examiner will note that Claim 17 has been amended to recite a specific list of diseases or conditions which may be treated using the compounds of the invention.

The Examiner is directed to page 1, lines 14 to 31 of the present application, which describes, with reference to scientific papers, the role of the H3 receptor in various

neurological diseases. This information would form part of the knowledge of the person of ordinary skill in the art at the filing date of the present application. The Examiner will readily appreciate that, at the filing date of the application, it had been demonstrated both *in vitro* and *in vivo* that H3 antagonists could be used to modulate the H3 receptor. Such antagonists could therefore be useful in the treatment of neurological diseases in which activity of the H3 receptor is implicated.

It is noted that there is no requirement in US patent law that animal model or clinical trial data are presented in the specification as filed in order to support the utility of novel compounds, see MPEP §2107.01, which states that:

> *"Similarly, courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition. The Federal Circuit, in Cross v. Iizuka, 753 F.2d 1040, 1051, 224 USPQ 739, 747-48 (Fed. Cir. 1985), commented on the significance of data from in vitro testing that showed pharmacological activity:*
>
> > *"We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question. Successful in vitro testing will marshal resources and direct the expenditure of effort to further in vivo testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an in vivo utility."*
>
> *The Federal Circuit has reiterated that therapeutic utility sufficient under the patent laws is not to be confused with the requirements of the FDA with regard to safety and efficacy of drugs to marketed in the United States."*

Therefore, it is sufficient that the scientific evidence, supported by *in vitro* data gives a plausible teaching that the compounds may be effective in treating diseases which are associated with activity at a particular receptor.

The Examiner has acknowledged that the specification teaches that the instant compounds have activity at the H3 receptor (see page 34, lines 10 to 15) and assays for testing H3 activity are also described (see page 31, line 20 to page 34, line 8).

Therefore, the person of ordinary skill in the art is able to prepare compounds within the scope of claim 1, and test them in *in vitro* assays to establish H3 activity. The data thus

obtained, together with the scientific evidence described in the specification, enables the person of ordinary skill in the art to make and use the compounds of the invention for the treatment of neurological diseases. Thus, the Applicant submits that the enablement requirement is met.

B. Claims 1-8, 10, 13, and 19 are Non-Obvious

Claims 1-8, 10, 13, and 19 were rejected under 35 USC §103(a) as being unpatentable over Patent No. DE4407139A1 (Thomae). Applicants respectfully traverse this rejection.

The Applicants note that Example 2 of Thomae, as identified by the Examiner, does not, in fact, meet all the limitations of instant claim 1. In Example 2 of Thomae, q represents 2, whereas instant claim 1 requires that q is 3 or 4. Furthermore, instant claim 1 requires –OR^3 to be present, whereas in Example 2 of Thomae, the group corresponding to R^3 in claim 1 is directly attached to the phenyl ring, i.e. there is no oxygen present. Thus, it is clear that there is no overlap in scope between the disclosure of Thomae in either the specific examples or the general teaching, and instant claim 1.

The compounds disclosed in Thomae are disclosed as inhibitors of chloresterol biosynthesis, and in particular as inhibitors of the enzyme 2,3-epoxysqualene-lanosterol-cyclase, and thus are useful for the treatment of diseases such as coronary heart disease, cerebral ischemia, intermittent claudication, gangrene, hyperproliferative skin disorders and gallstone complaints. The instant compounds are disclosed as being antagonists of the histamine H3 receptor, and thus are useful for the treatment of neurological diseases associated with the activity of the H3 receptor. Therefore, Thomae relates to not only different diseases, but also a different target.

It follows that a person of ordinary skill in the art would find no teaching, suggestion or motivation in Thomae to modify the compounds disclosed therein in order to arrive at a compound falling within the scope of instant claim 1 for the treatment of neurological diseases associated with histamine H3 activity.

C. Terminal Disclaimer Renders Double Patenting Rejection Moot

Claims 1-13, 17, and 19 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 11/246,480.

Applicants include herewith a terminal disclaimer, thus rendering the double patenting rejection moot. Withdrawl of the rejection is respectfully requested.

CONCLUSION

It is respectfully asserted that in view of the amendments and remarks made above, the case is now in condition for allowance. A Notice of Allowance is respectfully requested.

If any minor issues remain precluding such allowance, the Examiner is requested to contact Applicants' representative at the number below.

Respectfully submitted,

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